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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,146	03/31/2005	Martin A Smith	58142(45858)	2874

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EXAMINER	
TUNG, JOYCE	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
12/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,146	SMITH ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/2/08 has been entered.

The response filed 10/2/08 to the Office action has been entered. Claims 1-35 and 66 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-12, 14-35 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (WO 00/21973, issued April 20, 2000) in view of Burgoyne (5,496,562, issued March 5, 1996).

Mitchell et al. disclose the method steps (a)-(c) as recited in instant claim 1 (See pg. 2, third paragraph) and the method steps as recited in claim 4 (See pg. 2, third paragraph). The nucleic aid is retained by the filter substantially in the absence of ionic interaction (See column 2, last paragraph), and by physically retarding the movement of the nucleic acid down the filter (See pg. 3, first paragraph). The nucleic acid is heated to an elevated temperature, whilst retained by the filter prior to elution and the temperature is about 90^0C, (See pg. 3, second paragraph, pg. 6, first paragraph, pg. 12, first paragraph and pg. 25, experiment 6). There is a solution for rupturing intact whole cells to leave condensed nuclear material and a lysis solution for lysing nuclear material (See pg. 3, third paragraph). The sample comprises whole blood, which has been treated with a red blood cell lysis solution, whilst the white cells containing the nucleic acid are retained by the filter as a retentate (See pg. 6, third paragraph). The red blood cell lysis solution is listed in Table 2 (see pg. 17). The lysis solution includes a week base (Tris), a chelating agent (EDTA) (see pg. 17). A filter material is selected which provides no barrier to cells, but enables the cells to be retained by the filter as a retentate (See pg. 6, second paragraph). Sodium dodecyl sulfate is one of the detergents used with a concentration of 5% (see pg. 8, line 9). The pore size of the filter is 4.5um (See pg. 11, table1). The filter used in the method comprises a plurality of fibers and has a substantially disordered structure, the fiber diameters are selected from the range of 1um to 10 um (See pg. 9, fourth paragraph). The fiber is a glass fiber, silica based or plastic based fiber (See pg. 10, first paragraph). It is possible to isolate nucleic

acid in the absence of a chaotrope (See pg. 10, second paragraph). Genomic DNA is a desired target or nucleic acid is RNA (See pg. 15, fourth paragraph).

Mitchell et al. also indicate that if the filter is allowed to dry the nucleic acid still is recoverable, but may be sheared and the yield will be reduced. Where the method is carried out in a column, drying of the filter may be avoided by using a water vapour retarding or blocking seal (see pg. 7, lines 15-19).

Mitchell et al. do not disclose the method steps (f)-(g) as recited in instant claim 1 and that uric acid or a urate salt is used.

Burgoyne discloses that the blood-stained paper was dried, and sent through the ordinary mail so that it spent at least three days in the mail, and had the DNA extracted from it (See column 4, lines 41-45). A card loaded with a DNA sample is air dried at room temperature (See column 5, lines 43-44). A solid matrix comprises an absorbent cellulose based paper (such as filter paper) or a micromesh of synthetic plastic material (see column 2, lines 21-26).

Burgoyne also discloses the use of uric acid as a DNA protecting compound together with a weak base (see pg. 2, lines 53-58).

Mitchell et al. do not explicitly disclose the period of storing nucleic acid as recited in claims 6-9.

Burgoyne discloses that the blood-stained paper treated with detergent is stored for more than 36 months without DNA degradation (See column 4, lines 21-25).

One of ordinary skill in the art would have been motivated to apply the method steps of drying a solid phase medium with a cell lysate comprising nucleic acid and storing the dried solid phase medium with the nucleic acid as taught by Burgoyne because it would have been

useful for long term storage, such as 36 months (See column 4, lines 21-25) or four years (See column 5, lines 1-4). It would have been prima facie obvious to apply the method steps (f)-(g) as recited in instant claim 1.

Regarding claims 35 and 66, Mitchell et al. do not explicitly disclose adding a single solution to solid phase medium having a cellular retentate and the single solution simultaneously comprising; a weak base, a chelating agent and an anionic surfactant or detergent.

Burgoyne discloses a solid matrix for storage of blood DNA having a composition absorbed and that the composition comprises a weak base, a chelating agent and an anionic surfactant or detergent (see column 2, lines 59-64, column 3, and lines 18-26).

Therefore, one of ordinary skill in the art would have been motivated to add a single solution comprising a weak base, a chelating agent and an anionic surfactant or detergent to a solid medium having the cellular retentate as taught by Burgoyne because by doing so blood DNA can be stored for a long time and the DNA is extracted from a solid medium. It would have been prima facie obvious to apply a single solution simultaneously comprising; a week base, a chelating agent and an anionic surfactant or detergent to a solid phase medium having a cellular retentate.

Based upon the analysis above, the teachings of Mitchell et al. in view of the teachings of Burgoyne are again applied.

4. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (WO 00/21973, issued April 20, 2000) in view of Burgoyne (5,496,562, issued March 5, 1996) as applied to claims 1-12, 14-35 and 66 above, and further in view of Mullis (5,187,083, issued Feb, 16, 1993).

The teachings of Mitchell et al. and Burgoyne et al. are set forth in section 3 above. Mitchell et al. and Burgoyne do not disclose the size of the filter pore as recited in claim 13.

Mullis discloses a method for obtaining substantially purified DNA from a biological sample (See column 3, lines 21-22). The filter includes a surface that reversibly and specifically retains DNA. The pore size is from about 0.2 microns to about 0.8 microns. A preferred filter comprises a membrane filter comprised of cellulose acetate and nitrocellulose having a pore size of 0.45 microns (See column 3, lines 44-54, column 7, line 44-45, column 10, lines 16-29, column 15, lines 25).

One of ordinary skill in the art would have been motivated to apply the filter of Mullis with the pore size which is from about 0.2 microns to about 0.8 microns because the filter of Mullis is used in obtaining substantially purified DNA from a biological sample (See column 3, lines 21-22). It would have been prima facie obvious to apply the filter of Mullis with the pore size which is from about 0.2 microns to about 0.8 microns for isolating nucleic acid as claimed.

Summary

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

Joyce Tung
December 12, 2008